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APPLICATION NUMBER	FILING DATE	FIRST NAMED APPLICANT	ATTORNEY DOCKET NO.
09/236,468	01/25/99	SOPPET	D PF201D1
022195 HUMAN GENOME SCIENCES INC 9410 KEY WEST AVENUE ROCKVILLE MD 20850		HM22/0517	EXAMINER SPECTOR, L
			ART UNIT 1647
			PAPER NUMBER <i>16</i>
			DATE MAILED: 05/17/01

This is a communication from the examiner in charge of your application.
COMMISSIONER OF PATENTS AND TRADEMARKS

OFFICE ACTION SUMMARY

- Responsive to communication(s) filed on 4/27/01
- This action is FINAL.

- Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 D.C. 11; 453 O.G. 213.

A shortened statutory period for response to this action is set to expire 3 month(s), or thirty days, whichever is longer, from the mailing date of this communication. Failure to respond within the period for response will cause the application to become abandoned. (35 U.S.C. § 133). Extensions of time may be obtained under the provisions of 37 CFR 1.136(a).

Disposition of Claims

- Claim(s) 1, 10-12, 15-17, 19, 21-76 is/are pending in the application.
Of the above, claim(s) 1, 10-12, 15-17, 19 is/are withdrawn from consideration.
- Claim(s) 21-35, 70-76 is/are allowed.
- Claim(s) 36-69 is/are rejected.
- Claim(s) _____ is/are objected to.
- Claims 1, 10-12, 15-17, 19, 21-76 are subject to restriction or election requirement.

Application Papers

- See the attached Notice of Draftsperson's Patent Drawing Review, PTO-948.
- The drawing(s) filed on _____ is/are objected to by the Examiner.
- The proposed drawing correction, filed on _____ is approved disapproved.
- The specification is objected to by the Examiner.
- The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. § 119

- Acknowledgement is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d).
- All Some* None of the CERTIFIED copies of the priority documents have been received.
- received in Application No. (Series Code/Serial Number) _____.
- received in this national stage application from the International Bureau (PCT Rule 17.2(a)).

*Certified copies not received: _____

- Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).

Attachment(s)

- Notice of Reference Cited, PTO-892
- Information Disclosure Statement(s), PTO-1449, Paper No(s). 6
- Interview Summary, PTO-413
- Notice of Draftsperson's Patent Drawing Review, PTO-948
- Notice of Informal Patent Application, PTO-152

- SEE OFFICE ACTION ON THE FOLLOWING PAGES --

Part III: Detailed Office Action

The rejection of claims 29-36 and 44-50 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention (deposit requirement) is withdrawn in view of applicants statement of availability in paper number 15, filed 4/27/01.

Information Disclosure Statement:

Applicants have resubmitted References C7-C9 from the information disclosure statement filed 1/27/00, paper number 6, and the references have been considered. No determination of relevance of the sequences therein to the claimed invention can be made, as there is no alignment of such with the disclosed sequences.

15 Objections and Rejections under 35 U.S.C. §112:

The following is a quotation of the first paragraph of 35 U.S.C. 112:

20 The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 51-69 remain rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention for reasons cited in the previous Office Action, paper number 13 mailed 11/28/00, at page(s) 3. This is a new matter rejection.

Applicants arguments in paper number 15, filed 4/27/01, have been fully considered but are not deemed persuasive. Applicants argue that Figure 2 and the tabular representation of the sequence data submitted with paper number 10 is merely one of display, as figure 2 shows the analysis in a

graphic format, whereas the tabular representation of data shows the analysis in a numerical format. This argument has been fully considered but is not deemed persuasive because: (a) The numerical format, which is not part of the specification as originally filed, presents much more specific data than the graphical format, in that specific residue numbers are given whereas the graphical format, figure 5 2, which is a part of the specification as originally filed, shows peaks or blocks corresponding to motifs, over a range in which 50 amino acids are represented per linear centimeter. The Examiner does not accept the assertion that the same data could be gleaned from the figure, in which each individual amino acid is represented by 0.02 millimeters; such a scale is inadequate to allow determination of precisely which amino acid corresponds to the beginning of a motif. (b) Given that 10 the data of the table submitted with paper number 10 cannot be directly derived from the originally submitted Figure 2, it is not persuasive that because both the table and the figure were generated using the same software that the disclosure of the table is inherent to the disclosure of the figure. 35 U.S.C. §112, first paragraph requires that the specification as originally filed "contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable 15 any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same". The assertion that the necessary data could be calculated in the same fashion as was done for generating Figure 2 is not sufficient to meet this burden. Written description is not judged by what could be done, but rather by what was actually disclosed in the specification as originally filed. (c) Finally, even if, *in arguendo*, one could have determined which residues corresponded to which features 20 based upon a reading of figure 2, it remains that a characterization of various regions of the protein is *not* tantamount to a description of the fragments that applicant now wishes to claim. It is noted that Figure 2 shows 14 different plots of protein characteristics, and assigns no criticality to any particular fragments. A statement in the description of the figure that particular plots correspond to one another is not evidence of conception of particular fragments. It remains that the specific fragments 25 now claimed are simply not described in the specification as originally filed, and that the generic disclosure of antigenic portions of the protein, with no reference to particular regions as now claimed, coupled with a wish to make antibodies to such is insufficient to support the newly submitted claims.

Applicants further argue that *in ipsius verbis* support for the claims is not required to satisfy the written description provision of 35 U.S.C. §112, first paragraph. The Examiner takes no issue with the cited case law. However, the issues are substantively different; in *Unocal*, the issue was whether the specification provided adequate description for claims to gasoline formulations which were described in the claims by their properties, rather than a specific formula.

The court in *Unocal* (54 USPQ2d 1227) stated: "... this invention lends itself to description in terms of ranges and variance of those ranges to achieve particular properties of the gasoline products. The inquiry for adequate written description simply does not depend on a particular claim format, but rather on whether the patent's description would show those of ordinary skill in the petroleum refining art that the inventors possessed the claimed invention at the time of filing." And "The patent unmistakably informs skilled refiners to increase or decrease the various components to arrive at preferred combinations. In fact, the written description usually labels both preferred and most preferred levels within each range. Skilled refiners testified that they knew the composition of the claimed combinations based on this written description. Contrary to appellant refiners' arguments to this court, the record shows that refiners of ordinary skill understood and applied the '393 patent's teachings. In sum, the record shows that the inventors possessed the claimed invention at the time of filing in the assessment of those of ordinary skill in the petroleum refining art." (*Unocal* at 1233) "In this case, the patent teaches one of ordinary skill that reducing T50 progressively reduces CO and hydrocarbons; reducing olefins progressively reduces NOx and hydrocarbons; increasing paraffins progressively reduces CO and NOx; and so forth with several other relationships. Then the patent claims ranges for these properties that provide cleaner gasoline emissions. The Background and Abstract portions of the specification discuss thoroughly the claimed ranges and the combinations of multiple properties." (*Unocal* at 1234) Unlike the disclosure in *Unocal*, the instant disclosure does not discuss particular fragments that are seen as being useful for their antigenic properties, but rather discloses the broad concept of such fragments, and a series of plots, Figure 2, which show various properties of the protein, but in a fashion which would preclude identification of specific residues, for reasons cited above. The fragments claimed seem to have been derived from

the thirteen different plots of Figure 2, but how is not clear. The specific residues recited in, for example, claim 51, do not have clear basis; they do not strictly correspond to the limits of disclosed "antigenic regions" as seen on the Jameson-Wolf plot of Figure 2. There are no preferred ranges stated, nor even any preference as to which of the 13 plots should be consulted to determine appropriate antigenic fragments. Thus, the Examiner maintains that there is no basis in the specification as originally filed for the particularly claimed fragments.

The Examiner's position is supported by the case law. Applicants may not claim a specific thing not originally described merely because it comes within the scope of the genus disclosed. (See *Ex parte Klager*, 132 USPQ 207.) Arbitrarily designating a group of materials subgeneric to the group previously claimed which was not delineated or supported as such does not have basis (*see In re Welstead*, 174 USPQ 449, 450). In this case, although the general genus of antigenic fragments was disclosed and is enabled by the specification, the specific fragments which applicants now seek to claim were not.

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Claims 37-50 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for a protein having at least 90% identity to either SEQ ID NO: 2 or the protein encoded by the deposited plasmid (once the deposit has been perfected, see above), which protein either retains activity as a PTH receptor or binding protein or alternatively does not include novel epitopes not found in the protein of SEQ ID NO: 2 or that encoded by the deposited plasmid, does not reasonably provide enablement for proteins which do not retain the binding function of the disclosed protein and which include epitopes not native to the disclosed protein. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to use the invention commensurate in scope with these claims for reasons cited in the previous Office Action at page(s) 4-5.

Applicants traverse that the claims have been amended to recite that the claimed polypeptides

have "HLTDG74 biological activity." This argument has been fully considered but is not deemed persuasive because the term "HLTDG74 biological activity" is not defined in the specification, and to the extent that it may encompass other than activity as a PTH receptor or binding protein or alternatively activity as an antigen for the production of antibodies specifically reactive epitopes found in the protein of SEQ ID NO: 2 , such properties are not described in the specification as originally filed, and further, it would require undue experimentation to discover such properties and then determine what species of variants would reasonably be expected to retain such properties.

10 The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

15 Claims 37-50 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

 Claims 37 and 44 have been amended to recite "HLTDG74 biological activity." This term is not defined in the specification as originally filed, so that it is not clear to what possible activities such refers. The remaining claims are rejected for depending from an indefinite claim.

20 Claim 36 is drafted in product-by-process format, but fails to recite sufficient details of the process. For example, the claim recites 'culturing a host cell' without any specification of what the host cell is or may or may not have been transformed or transfected with. Amendment to recite that the host cell comprises a heterologous nucleic acid encoding the protein of claim 29 would be remedial.

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 Claims 21-35 and 70-76 are allowable.

Serial Number 09/236468
Art Unit 1647

Advisory Information:

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

5 A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

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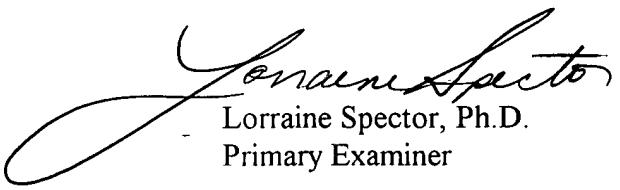
15 Any inquiry concerning this communication or earlier communications from the Examiner should be directed to Lorraine M. Spector, whose telephone number is (703) 308-1793. Dr. Spector can normally be reached Monday through Friday, 9:00 A.M. to 5:30 P.M.

If attempts to reach the Examiner by telephone are unsuccessful, the Examiner's supervisor, Gary Kunz, can be reached at (703)308-4623.

20 Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the Group receptionist at telephone number (703) 308-0196.

25 Certain papers related to this application may be submitted to Group 1600 by facsimile transmission. Papers should be faxed to Group 1600 via the PTO Fax Center located in Crystal Mall 1 (CM1). The faxing of such papers must conform with the notices published in the Official Gazette, 1156 OG 61 (November 16, 1993) and 1157 OG 94 (December 28, 1993) (see 37 C.F.R. § 1.6(d)). NOTE: If Applicant does submit a paper by fax, the original signed copy should be retained by applicant or applicant's representative. NO DUPLICATE COPIES SHOULD BE SUBMITTED so as to avoid the processing of duplicate papers in the Office.

30 Official papers filed by fax should be directed to (703) 305-4242. Faxed draft or informal communications with the examiner should be directed to (703) 308-0294. Please advise the Examiner at the telephone number above when an informal fax is being transmitted.

35 
Lorraine Spector, Ph.D.
Primary Examiner

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